

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION**

David J. Beyda,

Plaintiff,

VS.

DEPUY ORTHOPAEDICS, INC.;
JOHNSON & JOHNSON SERVICES, INC.;
and DOES 1-10, inclusive,

Defendants.

CIVIL ACTION NO. 3:12-cv-2521

JURY TRIAL DEMANDED

COMPLAINT FOR DAMAGES

Plaintiff David J. Beyda (“Plaintiff”), alleges on information and belief against DEPUY ORTHOPAEDICS, INC., JOHNSON & JOHNSON SERVICES, INC., and DOES 1-10, INCLUSIVE, (“Defendants”), the following:

I.

INTRODUCTION AND SUMMARY OF ACTION

1. Defendants manufactured the Pinnacle Acetabular Cup System (“Pinnacle Device”), and launched it in 2001. The Pinnacle Device was designed, developed, and sold for human hip joints damaged or diseased due to fracture, osteoarthritis, rheumatoid arthritis, and avascular necrosis. The Pinnacle Device is designed to be fastened to human bone with surgical screws. The Pinnacle Device was designed and sold to provide pain relief and consistent and smooth range of motion. Defendants marketed the Pinnacle Device as having significant advantages over other hip devices and hip replacement systems. Defendants marketed and

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1 described the Pinnacle Device as “[u]niquely designed to meet the demands of active patients
2 like you –and help reduce pain” and advertised it with pictures of a young woman trying on
3 sneakers in an athletic shoe store. Defendants advertised the Pinnacle Device as a superior
4 device featuring TrueGlide technology, allowing the body to create a thin film of lubrication
5 between surfaces, which enables “a more fluid range of natural motion.”

6 2. Defendants also advertised and sold the Pinnacle Device as the best surgical
7 option that “[r]ecreates the natural ball-and-socket joint of your hip, increasing stability and
8 range of motion.”

9 3. On information and belief Plaintiff alleges that Defendants sold approximately
10 150,000 Pinnacle Devices. Defendants have stated in promotional materials that “99.9% of
11 Pinnacle Hip components are still in use today.”

12 4. On information and belief, Plaintiff alleges that over 1,300 adverse reports have
13 been submitted to the U.S. Food and Drug Administration (FDA) regarding failures or
14 complications of the Pinnacle Device.

15 5. On information and belief, Plaintiff alleges that Defendants are aware that the use
16 of the Pinnacle Device may result in metallosis, biologic toxicity, and a high failure rate.
17 Plaintiff further alleges that use of the Pinnacle Device results in unsafe release of toxic metal
18 ions into hip implant recipients’ tissue and bloodstream. Plaintiff further alleges that Defendants
19 are aware that metal particles from the Pinnacle Device results in metallosis, tissue death, bone
20 erosion, and development of tumors.

21 6. On information and belief, Plaintiff alleges that particulate debris from the
22 Pinnacle Device causes severe inflammation, severe pain, tissue and bone loss, and other related
23 diseases.

24 7. Plaintiff further alleges that Defendants are aware that certain Pinnacle Device
25 recipients have elevated cobalt and chromium levels greatly exceeding acceptable safety
26 standards.

1
2 **II.**

3 **PARTIES**

4 8. Plaintiff David J. Beyda is, and at all times relevant to this Complaint was, a
5 resident of the city of Brooklyn, in the state of NY. On or about 4/12/2012, Plaintiff underwent a
6 right total hip arthroplasty procedure.

7 9. Defendant DEPUY ORTHOPAEDICS, INC. is, and at all times relevant to this
8 Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic
9 Drive, Warsaw, Indiana 46581. Defendant DEPUY ORTHOPAEDICS, INC. is and was at all
10 times relevant herein doing business in and/or having directed its activities at Texas, and
11 specifically this judicial district.

12 10. Defendant JOHNSON & JOHNSON SERVICES, INC. is, and at all times
13 relevant to this Complaint was, a New Jersey Corporation with its principal place of business at
14 One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON &
15 JOHNSON SERVICES, INC. is and was at all times relevant herein doing business in and/or
16 having directed its activities at Texas, and specifically this judicial district.

17 11. Plaintiff is unaware of the true names and capacities, whether individual,
18 corporate, associate, or otherwise, of defendants DOES 1-10, inclusive, or any of them, and
19 therefore sues these Defendants, and each of them, by such fictitious names. Plaintiff will seek
20 leave of this Court to amend this complaint when the status and identities of these Defendants are
21 ascertained.

22 12. At all times relevant herein, Defendants were the agents of each other, and in
23 doing the things alleged herein, each defendant was acting within the course and scope of its
24 agency and was subject to and under the supervision of its co-defendants.

25
26 **III.**

27 **JURISDICTION AND VENUE**

1 17. The Pinnacle Device is a Class III medical device. Class III devices are those
2 that operate to sustain human life, are of substantial importance in preventing impairment of
3 human health, or pose potentially unreasonable risks to patients.

4 18. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938
5 (“MDA”), in theory, require Class III medical devices, including the Pinnacle Device, to
6 undergo premarket approval by the FDA, a process which obligates the manufacturer to design
7 and implement a clinical investigation and to submit the results of that investigation to the FDA.

8 19. Premarket approval is a rigorous process that requires a manufacturer to submit
9 what is typically a multivolume application that includes, among other things, full reports of all
10 studies and investigations of the device’s safety and effectiveness that have been published or
11 should reasonably be known to the applicant; a full statement of the device’s components,
12 ingredients, and properties and of the principle or principles of operation; a full description of
13 the methods used in, and the facilities and controls used for, the manufacture, processing, and,
14 when relevant, packing and installation of, such device; samples or device components required
15 by the FDA; and a specimen of the proposed labeling.

16 20. The FDA may grant premarket approval only if it finds that there is reasonable
17 assurance that the medical device is safe and effective and must weigh any probable benefit to
18 health from the use of the device against any probable risk of injury or illness from such use.

19 21. A medical device on the market prior to the effective date of the MDA – a so-
20 called “grandfathered” device – was not required to undergo premarket approval. In addition, a
21 medical device marketed after the MDA’s effective date may bypass the rigorous premarket
22 approval process if the device is “substantially equivalent” to a “grandfathered” pre-MDA
23 device (i.e., a device approved prior to May 28, 1976). This exception to premarket approval is
24 known as the “510(k)” process and simply requires the manufacturer to notify the FDA under
25 section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device’s
26 introduction on the market, and to explain the device’s substantial equivalence to a pre-MDA
27 predicate device. The FDA may then approve the new device for sale in the United States.

1 22. Rather than being approved for use by the FDA pursuant to the rigorous
2 premarket approval process, the Pinnacle Device metal-on-metal total hip replacement system
3 was certified to be sold on the basis of Defendants' claim that, under section 510(k) of the
4 MDA, it was "substantially equivalent" to another older metal-on-metal hip implant device that
5 Defendants sold and implanted prior to the enactment of the MDA in 1976.

6 23. As such, under the 510(k) process, Defendants were able to market the Pinnacle
7 Device with virtually no clinical or non-clinical trials or FDA review of the implant for safety
8 and effectiveness.

9 C. **Defendants Took No Steps To Test The Pinnacle Device Or They Would**
10 **Have Discovered That It Leads To Metallosis And Other Complications**
11 **Before Releasing It On The Market**

12 24. Had Defendants conducted clinical trials of the Pinnacle Device before it was
13 first released on the market in the early 2000's, they would have discovered at that time what
14 they ultimately learned in and around 2007 – that the Pinnacle Device results in a high
15 percentage of patients developing metallosis, biologic toxicity and an early and high failure rate
16 due to the release of metal particles in the patient's surrounding tissue when the cobalt-
17 chromium metal formal head rotates within the cobalt-chromium metal acetabular liner.

18 25. In other words, implantation of the Pinnacle Device results in the nearly
19 immediate systemic release of high levels of toxic metal cobalt-chromium ions into every hip
20 implant patient's tissue and bloodstream. This is because cobalt-chromium metal particles are
21 released by friction from the metal femoral head rotating within the metal liner. The particles
22 then accumulate in the patient's tissue surrounding the implant giving rise to metallosis,
23 pseudotumors, or other conditions.

24 26. The formation of metallosis, pseudotumors, and infection and inflammation
25 causes severe pain and discomfort, death of surrounding tissue and bone loss, and a lack of
26 mobility.

27 27. The problems with the Pinnacle Device are similar to the issues that gave rise to
28 Defendants' recall of the ASR XL Acetabular System and ASR Hip Resurfacing System. Like

1 the Pinnacle Device, the ASR is also prone to early failure, and causes metallosis and cobalt
2 toxicity resulting in serious health problems and the need for subsequent revision surgery. As a
3 result, in August 2010, Defendants, in acknowledging the high failure rate of the ASR, recalled
4 more than 93,000 ASRs worldwide. It is anticipated that Defendants will at some point recall
5 Pinnacle Devices for the same reasons.

6 28. On information and belief, Plaintiff alleges that the FDA has received more than
7 1,300 adverse reports regarding problems associated with or attributed to the Pinnacle Device.

8 29. On information and belief, Plaintiff alleges that many recipients of the Pinnacle
9 Device are suffering from elevated levels of chromium and cobalt. Plaintiff further alleges on
10 information and belief that Defendants are aware that certain recipients of the Pinnacle Device
11 have significantly elevated levels of chromium and cobalt in amounts many times higher than
12 acceptable or recommended safety levels. Notably, the ASR and the Pinnacle Device were
13 designed by the same orthopaedic surgeon, Dr. Thomas Schmalzried.

14 30. A number of governmental regulatory agencies have recognized the problems
15 that are caused by metal-on-metal implants such as the ASR and Pinnacle Device. For instance,
16 The Medicines and Healthcare Products Regulatory Agency (“MHRA”) in Britain investigated
17 Defendants’ metal-on-metal total hip replacement system after receiving widespread reports of
18 soft tissue reactions and tumor growth in thousands of patients who had received these implants.
19 MHRA has required physicians to establish a system to closely monitor patients known to have
20 metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to
21 evaluate them for related soft tissue reactions.

22 31. Similarly, the Alaska Department of Health recently issued a bulletin warning of
23 the toxicity of Defendants’ metal-on-metal total hip replacement systems. The State of Alaska,
24 like the MHRA, identified the need for close medical monitoring, surveillance and treatment of
25 all patients who had received these and similar metal-on-metal implants.

26 32. Despite the public knowledge to the contrary, Defendants’ continue to
27 misrepresent the Pinnacle Device as a high-quality, safe and effective hip replacement product
28

1 in their marketing and promotional materials. This is despite the fact that Defendants have
2 known for years that the Pinnacle Device poses a danger to patients that have it implanted.

3 33. As a result, Defendants continue to sell the Pinnacle Device to doctors who
4 implant them in countless numbers of patients with an unreasonably high percentage of those
5 patients being forced to endure serious injury from metallosis, pseudotumors, and biologic
6 toxicity, among other complications. These patients are reporting severe pain and discomfort
7 and the need for one or more complicated revision surgeries resulting in life-long health
8 problems caused by the defective device.

9 **D. Plaintiff Was Implanted With A Pinnacle Device And As A Result Has**
10 **Suffered Severe Injuries**

11 34. On or about 4/12/2012, Plaintiff underwent a right total hip arthroplasty
12 procedure. A Pinnacle Device with an Ultamet liner was implanted in place of his right hip.

13 35. After the surgery, friction and wear between the cobalt-chromium metal head
14 and cobalt-chromium metal liner caused large amounts of toxic cobalt-chromium metal ions and
15 particles to be released into Plaintiff's blood and tissue and bone surrounding the implant. As a
16 result, Plaintiff has been experiencing severe pain and discomfort and inflammation in his right
17 thigh and groin. Plaintiff also experiences a popping and snapping sensation in his hip-joint
18 when walking or moving to and from a sitting position.

19 36. Due to Plaintiff's chronic pain and discomfort and other symptoms, Plaintiff will
20 likely need to undergo revision surgery to replace the implant.

21 37. All of the injuries and complications suffered by Plaintiff were caused by the
22 defective design, warnings, construction and unreasonably dangerous character of the Pinnacle
23 Device that was implanted in Plaintiff. Had Defendants not concealed the known defects, the
24 early failure rate, the known complications and the unreasonable risks associated with the use of
25 the Pinnacle Device, Plaintiff would not have consented to the Pinnacle Device being used in
26 his total hip arthroplasty.

27 38. Plaintiff was unaware of any causal link between the injuries he has suffered and
28 any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle

Device, due in part to the failures of Defendants to properly warn Plaintiff and his physicians about the Pinnacle Device's defective and faulty nature. In and around late fall, 2010, Plaintiff first became aware of said causal link when he became aware of the recall of the ASR by watching the nightly news on television and realized that the issues he had had with his Pinnacle Device were eerily similar to that which was being reported regarding the ASR. Plaintiff was unable to make an earlier discovery of said causal link despite reasonable diligence because of Defendants' failure to properly warn Plaintiff and his physicians about the Pinnacle Device's defective and faulty nature, and their failure to issue any recall or take any other proactive action to date with respect to the injuries being caused to patients that have been implanted with a Pinnacle Device.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants)

39. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

40. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the Pinnacle Device into the stream of commerce, including a duty to assure that the device would not cause those who had it surgically implanted to suffer adverse harmful effects from it.

41. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the Pinnacle Device into interstate commerce in that Defendants knew or should have known that those individuals that had the device surgically implanted were at risk for suffering harmful effects from it including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are

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1 permanent and lasting in nature, physical pain and mental anguish, including diminished
2 enjoyment of life, as well as the need for a revision surgery to replace the device with the
3 attendant risks of complications and death from such further surgery.

4 42. The negligence of Defendants, their agents, servants, and/or employees, included
5 but was not limited to the following acts and/or omissions:

6 a. Negligently designing the Pinnacle Device in a manner which was
7 dangerous to those individuals who had the device surgically implanted;

8 b. Designing, manufacturing, producing, creating, and/or promoting the
9 Pinnacle Device without adequately, sufficiently, or thoroughly testing it;

10 c. Not conducting sufficient testing programs to determine whether or not the
11 aforesaid Pinnacle Device was safe for use;

12 d. Defendants herein knew or should have known that Pinnacle Device was
13 unsafe and unfit for use by reason of the dangers to its users;

14 e. Selling the Pinnacle Device without making proper and sufficient tests to
15 determine the dangers to its users;

16 f. Negligently failing to adequately and correctly warn Plaintiff or their
17 physicians, hospitals and/or healthcare providers of the dangers of Pinnacle Device;

18 g. Negligently failing to recall their dangerous and defective Pinnacle Device
19 at the earliest date that it became known that the device was, in fact, dangerous and defective;

20 h. Failing to provide adequate instructions regarding safety precautions to be
21 observed by surgeons who would reasonably and foreseeably come into contact with, and more
22 particularly, implant the Pinnacle Device into their patients;

23 i. Negligently advertising and recommending the use of the Pinnacle Device
24 despite the fact that Defendants knew or should have known of its dangerous propensities;

25 j. Negligently representing that the Pinnacle Device offered was safe for use
26 for its intended purpose, when, in fact, it was unsafe;
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1 k. Negligently manufacturing the Pinnacle Device in a manner which was
2 dangerous to those individuals who had it implanted;

3 l. Negligently producing the Pinnacle Device in a manner which was
4 dangerous to those individuals who had it implanted;

5 m. Negligently assembling the Pinnacle Device in a manner which was
6 dangerous to those individuals who had it implanted;

7 n. Defendants under-reported, underestimated and downplayed the serious
8 danger of the Pinnacle Device.

9 43. Defendants were negligent in the designing, researching, supplying,
10 manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and
11 sale of the Pinnacle Device in that they:

12 a. Failed to use due care in designing and manufacturing the Pinnacle Device
13 so as to avoid the aforementioned risks to individuals that had the devices surgically implanted;

14 b. Failed to accompany their product with proper warnings;

15 c. Failed to accompany their product with proper instructions for use;

16 d. Failed to conduct adequate testing, including pre-clinical and clinical
17 testing and post-marketing surveillance to determine the safety of the Pinnacle Device; and

18 e. Were otherwise careless and/or negligent.

19 44. Despite the fact that Defendants knew or should have known that the Pinnacle
20 Device caused harm to individuals that had the device surgically implanted, Defendants
21 continued to market, manufacture, distribute and/or sell the Pinnacle Device.

22 45. Defendants knew or should have known that consumers such as Plaintiff would
23 suffer foreseeable injury, and/or be at increased risk of suffering injury as a result of
24 Defendants' failure to exercise ordinary care, as set forth above.

25 46. Defendants' negligence was the proximate cause of Plaintiff's physical, mental
26 and emotional injuries and harm, and economic loss which she has suffered and/or will continue
27 to suffer.
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1 in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as
2 the need for a revision surgery to replace the device with the attendant risks of complications
3 and death from such further surgery.

4 54. Further, as a result of the foregoing acts and omissions, Plaintiff suffered a loss
5 of wages and will in the future suffer a diminished capacity to earn wages.

6 55. In performing the foregoing acts and omissions, Defendants acted despicably,
7 fraudulently, and with malice and oppression so as to justify an award of punitive and
8 exemplary damages.

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10 **THIRD CAUSE OF ACTION**

11 **STRICT PRODUCTS LIABILITY (DESIGN DEFECT)**

12 **(Against All Defendants)**

13 56. Plaintiff incorporates by reference, as if fully set forth herein, each and every
14 allegation set forth in the preceding paragraphs and further allege as follows:

15 57. At all times herein mentioned, Defendants designed, researched, manufactured,
16 tested, advertised, promoted, marketed, sold, and/or distributed the Pinnacle Device as
17 hereinabove described that was surgically implanted in Plaintiff.

18 58. At all times herein mentioned, the Pinnacle Device designed, researched,
19 manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants
20 was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users
21 such as Plaintiff that had the device surgically implanted.

22 59. At all times herein mentioned, the Pinnacle Device designed, researched,
23 manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants
24 was in an unsafe, defective, and inherently dangerous condition at the time it left Defendants'
25 possession.

26 60. At all times herein mentioned, the Pinnacle Device was expected to and did
27 reach the usual consumers, handlers, and persons coming into contact with said product without
28

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1 substantial change in the condition in which it was designed, produced, manufactured, sold,
2 distributed, and marketed by Defendants.

3 61. At all times herein mentioned, the Pinnacle Device's unsafe, defective, and
4 inherently dangerous condition was a cause of injury to Plaintiff.

5 62. At all times herein mentioned, the Pinnacle Device failed to perform as safely as
6 an ordinary consumer would expect when used in an intended or reasonably foreseeable
7 manner.

8 63. Plaintiff's injuries resulted from use of the Pinnacle Device that was both
9 intended and reasonably foreseeable by Defendants.

10 64. At all times herein mentioned, the Pinnacle Device posed a risk of danger
11 inherent in the design which outweighed the benefits of that design.

12 65. At all times herein mentioned, the Pinnacle Device was defective and unsafe, and
13 Defendants knew or had reason to know that said product was defective and unsafe, especially
14 when used in the form and manner as provided by Defendants.

15 66. Defendants knew, or should have known, that at all times herein mentioned that
16 the Pinnacle Device was in a defective condition, and was and is inherently dangerous and
17 unsafe.

18 67. At the time of the implantation of the Pinnacle Device into Plaintiff, the
19 aforesaid product was being used for the purposes and in a manner normally intended, namely
20 for use as a hip replacement device.

21 68. Defendants, with this knowledge, voluntarily designed their Pinnacle Device in a
22 dangerous condition for use by the public and, in particular, Plaintiff.

23 69. Defendants had a duty to create a product that was not unreasonably dangerous
24 for its normal, intended use.

25 70. Defendants designed, researched, manufactured, tested, advertised, promoted,
26 marketed, sold and distributed a defective product which, when used in its intended or
27 reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to
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1 Plaintiff, in particular, and Defendants are therefore strictly liable for the injuries sustained by
2 Plaintiff.

3 71. As a direct and proximate result of Defendants' placement of the defective
4 Pinnacle Device into the stream of commerce, Plaintiff experienced and/or will experience
5 severe harmful effects including but not limited to partial or complete loss of mobility, loss of
6 range of motion, as well as other severe and personal injuries which are permanent and lasting
7 in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as
8 the need for a revision surgery to replace the device with the attendant risks of complications
9 and death from such further surgery.

10 72. Further, as a result of the foregoing acts and omissions, Plaintiff suffered a loss
11 of wages and will in the future suffer a diminished capacity to earn wages.

12 73. In performing the foregoing acts and omissions, Defendants acted despicably,
13 fraudulently, and with malice and oppression so as to justify an award of punitive and
14 exemplary damages.

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16 **FOURTH CAUSE OF ACTION**

17 **STRICT PRODUCTS LIABILITY (INADEQUATE WARNING)**

18 **(Against All Defendants)**

19 74. Plaintiff incorporates by reference, as if fully set forth herein, each and every
20 allegation set forth in the preceding paragraphs and further allege as follows:

21 75. Defendants designed, manufactured, tested, marketed and distributed into the
22 stream of commerce the Pinnacle Device.

23 76. The Pinnacle Device placed into the stream of commerce by Defendants was
24 defective due to inadequate warning, because Defendants knew or should have known that the
25 Pinnacle Device could fail early in patients therefore give rise to physical injury, pain and
26 suffering, debilitation, and the need for a revision surgery to replace the device with the
27 attendant risks of complications and death from such further surgery, but failed to give
28 consumers adequate warning of such risks. Further, the Pinnacle Device placed into the stream

Complaint for Damages

1 of commerce by Defendants was surgically implanted in a manner reasonably anticipated by
2 Defendants.

3 77. As a direct and proximate result of Defendants' placement of the defective
4 Pinnacle Device into the stream of commerce, Plaintiff experienced and/or will experience
5 severe harmful effects including but not limited to partial or complete loss of mobility, loss of
6 range of motion, as well as other severe and personal injuries which are permanent and lasting
7 in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as
8 the need for a revision surgery to replace the device with the attendant risks of complications
9 and death from such further surgery.

10 78. Further, as a result of the foregoing acts and omissions, Plaintiff suffered a loss
11 of wages and will in the future suffer a diminished capacity to earn wages.

12 79. In performing the foregoing acts and omissions, Defendants acted despicably,
13 fraudulently, and with malice and oppression so as to justify an award of punitive and
14 exemplary damages.

15
16 **FIFTH CAUSE OF ACTION**
17 **BREACH OF EXPRESS WARRANTY**
18 **(Against All Defendants)**

19 80. Plaintiff incorporates by reference, as if fully set forth herein, each and every
20 allegation set forth in the preceding paragraphs and further allege as follows:

21 81. Defendants designed, manufactured, tested, marketed and distributed into the
22 stream of commerce the Pinnacle Device.

23 82. Defendants expressly warranted that the Pinnacle Device was a safe and effective
24 hip replacement system.

25 83. The Pinnacle Device placed into the stream of commerce by Defendants did not
26 conform to these express representations because they failed early thereby giving rise to
27 unnecessary physical injury, pain and suffering, debilitation, and the need for a revision surgery
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1 to replace the device with the attendant risks of complications and death from such further
2 surgery.

3 84. As a direct and proximate result of Defendants' breach of express warranties
4 regarding the safety and effectiveness of the Pinnacle Device, Plaintiff has suffered significant
5 damages, including but not limited to physical injury, economic loss, pain and suffering, and the
6 need for further surgery to replace the faulty device, and will continue to suffer such damages in
7 the future.

8 85. In taking the actions and omissions that caused these damages, Defendants were
9 guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive
10 damages.

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12 **SIXTH CAUSE OF ACTION**

13 **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

14 **(Against All Defendants)**

15 86. Plaintiff incorporates by reference, as if fully set forth herein, each and every
16 allegation set forth in the preceding paragraphs and further allege as follows:

17 87. Defendants designed, manufactured, tested, marketed and distributed into the
18 stream of commerce the Pinnacle Device.

19 88. At the time Defendants designed, manufactured, tested, marketed and distributed
20 into the stream of commerce the Pinnacle Device, Defendants knew the use for which the
21 Pinnacle Device was intended, and impliedly warranted the Pinnacle Device to be of
22 merchantable quality and safe for such use.

23 89. Plaintiff reasonably relied upon the skill and judgment of Defendants as to
24 whether the Pinnacle Device was of merchantable quality and safe for its intended use.

25 90. Contrary to Defendants' implied warranties, the Pinnacle Device was not of
26 merchantable quality or safe for its intended use, because the Pinnacle Device was unreasonably
27 dangerous as described above.

28 **Complaint for Damages**

1 91. As a direct and proximate result of Defendants' breach of implied warranties
2 regarding the safety and effectiveness of the Pinnacle Device, Plaintiff has suffered significant
3 damages, including but not limited to physical injury, economic loss, pain and suffering, and the
4 need for further surgery to replace the faulty device, and will continue to suffer such damages in
5 the future.

6 92. In taking the actions and omissions that caused these damages, Defendants were
7 guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive
8 damages.

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10 **SEVENTH CAUSE OF ACTION**
11 **NEGLIGENT MISREPRESENTATION**
12 **(Against All Defendants)**

13 93. Plaintiff incorporates by reference, as if fully set forth herein, each and every
14 allegation set forth in the preceding paragraphs and further allege as follows:

15 94. The Defendants supplied false information to the public, to Plaintiff and to his
16 physicians regarding the high-quality, safety and effectiveness of the Pinnacle Device.
17 Defendants provided this false information to induce the public, Plaintiff and his physicians to
18 purchase and implant a Pinnacle Device.

19 95. The Defendants knew or should have known that the information they supplied
20 regarding the purported high-quality, safety and effectiveness of the implant to induce Plaintiff
21 and his physicians to purchase and use a Pinnacle Device was false.

22 96. The Defendants were negligent in obtaining or communicating false information
23 regarding the purported high-quality, safety and effectiveness of the Pinnacle Device.

24 97. Plaintiff and his physicians relied on the false information supplied by the
25 Defendants to his detriment by causing the Pinnacle Device to be purchased and implanted in
26 Plaintiff.
27
28

/s/ Franklin D. Azar

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JURY DEMAND

Plaintiff David J. Beyda hereby demands a trial by jury.

/s/ Franklin D. Azar

Franklin D. Azar

W. Mark Lanier

Tonya L. Melnichenko

Robert O. Fischel

Nathan J. Axvig

Kenneth S. Soh

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